Rad-8™

Signal Extraction Pulse Oximeter

Service Manual

Masimo SET®

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Service Manual

The Rad-8™ Service Manual is intended to provide the necessary information for proper servicing of the Rad-8™ pulse oximetry system. This manual is structured to support troubleshooting to the assembly or module level. This manual does not provide instructions for troubleshooting to the printed circuit board component level. There may be information provided in this manual that is not relevant for your system. Do not service the Rad-8 pulse oximeter without completely reading and understanding these instructions.

Fuse (F1, F2) Rating: 2A, 250V, Slow Blow, Surface, RoHS (Approvals: UL 248-14, CSA C22.2 no. 248.14. Compliance).

Fuse (F3) Rating: 1A, 250V, Slow Blow, Surface, RoHS (Approvals: UL 248-14, CSA C22.2 no. 248.14. Compliance).

Other specifications for Performance, Accuracy, Electrical and Environmental can be found in Section 7 of the Rad-8 Operator's Manual.

CAUTION:
Federal law (U.S.) restricts this device to sale by or on the order of a physician

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Made in USA.

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VueLink is the property of its owner.

Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 7,221,971, 7,215,986, 7,215,984, 6,850,787, 6,826,419, 6,816,741, 6,745,060, 6,699,194, 6,684,090, 6,654,624, 6,650,917, 6,643,530, 6,606,511,6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international equivalents, or one or more of the patents referenced at www.masimo.com/patents.htm. Other patents pending.

Other patents pending.

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1. Overview

1.1. About this Manual

This manual explains how to service the Rad-8 class of pulse oximeters. However, when a differentiation between models is required, the actual model type will be identified prior to the explanation (For example, the difference between a Rad-8H (Horizontal) or Rad-8V (Vertical). Important safety information relating to general use of the Rad-8 class of pulse oximeters appears in the Rad-8 Operator's Manual. Other important safety information is located throughout this manual where appropriate.

1.2. Warnings, Cautions and Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels is as follows:

A **warning** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of Warning:

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

A **caution** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

Sample of Caution:

CAUTION: This is a sample of a Caution statement.

A **note** is provided when extra general information is applicable.

Sample of Note:

Note: This is a sample of a Note statement.

2. Maintenance

2.1. Introduction

2.1.1. This chapter covers, how to test the operation of the Rad-8 oximeters, how to properly clean, how to replace the battery and how to obtain service under normal operation. No internal adjustment or recalibration is required. Service should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

WARNING: BEFORE CLEANING THE OXIMETER, TURN THE UNIT OFF.

2.2. Cleaning

2.2.1. To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

2.2.2. To clean the outer surface of the oximeter, the following solutions may be used to wipe the instrument for 30 seconds. *Do not allow liquids to enter the interior of the instrument.*

- Glutaraldehyde Solution
- Ammonium Chloride Wipe
- 10% Chlorine bleach in H2O
- 70% Isopropyl alcohol

CAUTION:

- Do not autoclave, pressure sterilize, or gas sterilize this oximeter.
- Do not spray, soak, or immerse the monitor in any liquid.
- Use the cleaning solution sparingly. Allow unit to air dry. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials and device failure can result.

3. Battery Operation and Maintenance

3.1. Overview

3.1.1. The Rad-8 oximeter uses a 6 volt, 1.4AHr lead acid, sealed, rechargeable battery.

3.1.2. Please reference the Rad-8 Operator's Manual for specifications on battery charge time and capacity.

3.2. Replacing the Batteries

3.2.1. Turn the Rad-8 oximeter off and remove the patient cable connection.

3.2.2. Place the unit on its side with the rubber footings facing up.

3.2.3. Remove the four screws from the housing assembly.

3.2.4. Carefully remove the speaker-side housing assembly. **DO NOT pull housing away as it may damage the speaker cable.**

3.2.5. Remove the speaker connector from the system board and set the housing aside.

3.2.6. Carefully lift the battery out of the housing and remove the positive and negative battery connections.

3.2.7. Install the replacement battery. Verify proper positioning of the (+) positive and (-) negative connectors. Reverse steps 3.2.3 through 3.2.6 to reassemble.

3.2.8. Verify the unit turns on, that all the LEDs momentarily light (AC LED will not illuminate when powering on with battery power only), that the low battery LED is not illuminated, and that the unit stabilizes to a normal operation mode.

CAUTION: Follow local governing guidelines for proper disposal of internal batteries. Do not incinerate.

4. Performance verification

To test the performance of the Rad-8 pulse oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Rad-8 fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.

4.1. Power-On Self-Test

4.1.1. With Rad-8 plugged into an AC power source and no cable or sensor plugged into the instrument, turn the monitor on by depressing the Power Button. For about 2 seconds all available LEDs are illuminated and a brief beep tone sounds. The unit will then cycle through Saturation and Pulse alarm limits.

4.1.2. After this initialization “boot” cycle, the No Sensor, Alarm Suspend and Normal Sensitivity Mode LED indicator’s will light. Also, the %SpO2 and BPM monitoring display will indicate “NO SEN”. The oximeter is ready to begin normal operation.

4.1.3. Turn power off and then back on as many times as necessary to verify this Power-On cycle.

4.2. Key Press Button Test

4.2.1. With the exception of the Power Button, press each button and verify that the oximeter acknowledges each key-press with an audible beep tone or by indicating a change on the display.

4.3. Serial Port Test

4.3.1. Using an IBM compatible computer, connect a straight through serial cable from the serial connection on your computer to the serial port on the rear of the Rad-8.

4.3.2. Initiate Hyper Terminal on your computer.

4.3.3. Setup Hyper Terminal using COM 1, then set Bits Per Second to 9600, data bits 8, Parity NONE, Stop Bits 1, Flow Control NONE.

4.3.4. From Setup Menu level 5 on the Rad-8, press the NEXT button for Serial Out and use the up/down arrows to select AS1(ASCII 1). Press “Mode/Enter” to start ASCII output.

4.3.5. Connect either a Masimo Tester or cable and sensor and verify output of Date, Time, SPO2%, BPM, PI, ALARM and EXC.

4.4. Sensor Test

4.4.1. Insert a known good Oximeter Tester into the sensor connector.

4.4.2. Turn power on.

4.4.3. Wait approximately 10 sec for the SpO2 and Pulse Rate displays to produce a number. During that time, the display should show “SEN OFF” and then dashes.

4.4.4. Read the SpO2 value from the display, and verify it is within the specified limits(%SpO2: 78 <= 84; BPM 60 <= 62).

4.5. Alarm Suspend Indicator

4.5.1. Induce an alarm condition.

4.5.2. Press the Alarm Suspend button and cycle through the 2 different indicator levels: yellow LED is Blinking or Off.

4.6. Alarm Volume Test

4.6.1. Press the Mode/Enter button. Monitor displays should show “AL” and “VOL”.

4.6.2. Press the UP arrow button and cycle through the three different volume levels. Make sure the tone does not have a harsh or raspy tone due to the speaker rattling in the plastic housing. The tone heard should be louder with each press. Press the DOWN arrow button and cycle through the different volume levels. The tone heard should be quieter with each press. Verify both speakers are working.

4.6.3. Return the volume to the factory default level 1.

4.7. Button Volume Test

4.7.1. Press the Mode / Enter button 2 times. LED displays should show “888” and “888”.

4.7.2. Press the Next arrow key. LED displays should show “but” and “VOL”.

4.7.3. Press the UP arrow button and cycle through the different volume levels. Make sure the tone does not have a harsh or raspy tone due to the speaker rattling in the plastic housing. The tone heard should be louder with each press. Press the DOWN arrow button and cycle through the different volume levels. The tone heard should be quieter with each press. There are three volume levels and volume off.

4.7.4. Return the volume to the factory default level 2.

4.8. Brightness Test

4.8.1. Press the Mode / Enter button 2 times. LED displays should show “888” above and “888” below.

4.8.2. Press the Down arrow button and cycle down through the different brightness levels. Press the Up arrow button and cycle up through the different brightness levels. There are four brightness levels.

4.8.3. Press the Mode / Enter button 4 times to return to patient monitoring mode or wait for display to time out.

4.9. Trauma Mode Test

4.9.1. Press the Trauma button. The Max sensitivity and FastSat LEDs should light.

4.9.2. Press the Trauma button again and the Max and FastSat LEDs should extinguish.

4.10. Sensitivity Mode

4.10.1. Press the Sensitivity button to alternately light the APOD, NORM, and MAX LEDs.

4.11. Fast Sat Mode test

4.11.1. Press the FastSat button. The FastSat LED should light.

4.11.2. Press the FastSat button again and the FastSat LED should extinguish.

Note: Selecting the FastSat averaging button **will not** automatically set the sensitivity mode to Max sensitivity.

4.12. Alarm Limit Test

4.12.1. With the monitor turned on, depress the ALARM LIMITS button and enter alarm menu. Change the High Saturation Alarm parameter to a value two points below the currently selected value, and accept the change by pressing the Mode/Enter button.

4.12.2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display.

4.12.3. Return the High Saturation Alarm parameter to its original setting and accept the change by pressing the Mode/Enter button.

4.12.4. Repeat steps 4.12.1 to 4.12.3 with the Low Saturation Alarm parameter.

4.12.5. Repeat steps 4.12.1 to 4.12.3 with the Low and High Pulse Rate Alarm parameter.

4.12.6. Reset the alarm limits again to the original settings and accept the changes by pressing the Mode/Enter button.

4.13. Date and Time Setting

4.13.1. Press the Mode / Enter button 4 times and verify that “Set CL” message appears on the display.

4.13.2. Press the Next arrow key and “Yr XX” will be displayed.

4.13.3. Verify that correct year is displayed.

4.13.4. Use Up / Down arrow buttons to set accordingly.

4.13.5. Press the Next arrow key and “nn XX” will be displayed.

4.13.6. Verify that correct month is displayed.

4.13.7. Use Up / Down arrow buttons to set accordingly.

4.13.8. Press the Next arrow key and “dAY XX” will be displayed.

4.13.9. Verify that correct day is displayed.

4.13.10. Use Up / Down arrow buttons to set accordingly.

4.13.11. Press the Next arrow key and “Hr XX” will be displayed.

4.13.12. Verify that correct hour is displayed.

4.13.13. Use Up / Down arrow buttons to set accordingly.

4.13.14. Press the Next arrow key and “nn XX” will be displayed.

4.13.15. Verify that correct minute is displayed.

4.13.16. Use Up / Down arrow buttons to set accordingly.

4.13.17. Press the Mode / Enter button.

4.13.18. Cycle power and verify the settings.

4.13.19. Turn power off.

5. Repair

5.1. Safety Precautions:

WARNING: When removing or installing any internal electrical components, be sure to first disconnect at least one terminal of the battery. **Verify reconnection of battery prior to reassembly of unit for patient monitoring.**

WARNING: ENSURE THE UNIT HAS BEEN CLEANED PER THE CLEANING INSTRUCTIONS IN SECTION 2.2.

5.2. General Procedures

5.2.1. Inspect the unit for cosmetic damage prior to disassembly or troubleshooting. External damage may be helpful in determining the root cause of the failure.

5.2.2. Note any markings or labeling on the unit that may have been placed by the end user. Duplicate or transfer this information in the event the housing or ancillary components are replaced.

5.2.3. Make note of the unit's serial number.

5.2.4. Make note of the software versions in the event the Oximeter board or system boards are replaced. These boards require software updates to make them compatible with the end user's version of software.

5.2.5. Contact Masimo Corporation using the information in Section 5.6.11 to research warranty history.

5.3. Troubleshooting

5.3.1. The troubleshooting procedures in this manual instruct the technician to isolate the failure down to the sub-assembly level. The intention is to have the Unit Under Test (UUT) repaired with minimal steps. The Masimo SET Tester is needed to perform the Performance Verification in Section 1 upon completion of repairs.

Note: The Masimo SET Tester is not a calibrated device. It is to be used for evaluation purposes only and not to determine if an oximeter is "calibrated".

5.3.2. Tools required are as follows:

Phillips head screwdriver #1
Multimeter

5.3.3. The troubleshooting steps below are presented in order of the most probable cause first. Proceed to the next step only if the unit continues to fail.

Symptom	Cause and Corrective Action Steps
• **Speaker Alarming (very loud) and unit is not functioning or displaying.**	• **Probable Watchdog error.** 1. Replace System board. 2. Replace User Interface board.
• **Alarm LED does not Illuminate** 1. Unit must be in alarm state. 2. Audible alarm can be heard.	1. Replace User Interface board. 2. Replace Display board.
• **Alarm Condition But No Audible Indication.** 1. Unit is in alarm condition.	1. Replace Speaker. 2. Replace System board.
• **Display Missing Segments**	1. Replace User Interface board. 2. Replace Display board.
• **Button Function Error** 1. Any front panel button Affected. 2. Buttons do not activate feature.	1. Replace Keypad. 2. Replace User Interface board.
• **"No Sen", or "Sen Off" Displayed.** 1. Cable is connected with sensor attached.	1. Replace sensor. 2. Replace patient cable. 3. Replace flex cable. 4. Replace oximeter board.
• **Unit Will Not Turn Off**	1. Replace Keypad. 2. Replace System board.

If unable to repair unit, then please call (800)326-4890 option #2 to arrange for return to Masimo Corporation.

5.4. Service Messages:

Upon detection of a system error, the main software alerts the user with an audible alarm indicator and displays the appropriate error code on the display. The MS board is held in reset and no other runtime functionality is available to the user until the unit is power cycled or until power is completely removed and re-applied to the system (removal and/or replacement of battery).

System Error	System Error Code
MS board communication Failure	1
MS board Diagnostics Failure	2
User Interface Waveform Overwrite	3
Sound Processor Waveform Overwrite	4
Main Processor Waveform Overwrite	5
Sat Pulse Rate Update Failure User Interface	6
Sat Pulse Rate Update Failure Sound Processor	7
User Interface One Time Command Overwrite	8
Sound Processor One Time Command Overwrite	9
Main Processor One Time Command Overwrite	10
Vor Voltage Error	11
Vbatt Voltage Error	12
V5 Voltage Error	13
Vcc Voltage Error	14
User Interface Revision Table Mismatch	15
Sound Processor Revision Table Mismatch	16

5.5. Repair Policy

5.5.1. Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. The product must be repaired.

5.5.2. Please clean contaminated/dirty equipment before returning. Make sure it is fully dry before packing the equipment.

5.5.3. To return the unit for service, please follow the Return Procedure outlined in this section.

5.6. Return Procedure

5.6.1. Please clean contaminated/dirty equipment before returning and make sure it is completely dry before packing the equipment.

5.6.2. Recommended decontamination procedure for equipment that has the potential for being exposed to blood or other potentially infectious materials.

5.6.2.1. Put on Lab coat or other protective garment.

5.6.2.2. Put on gloves.

5.6.2.3. Place equipment on the designated decontamination table.

5.6.2.4. Apply cleaning agent (10% bleach to water solution) to paper towel or use Cidex wipes.

5.6.2.5. Wipe down all aspects of the equipment.

5.6.2.6. Let the equipment air dry completely.

5.6.2.7. Remove gloves.

5.6.2.8. Move equipment to the area designated for equipment that has been through the decontamination process.

5.6.2.9. Dispose of all contaminated products properly.

5.6.3. Package the equipment securely – in the original shipping container if possible – and enclose the following information and items:

5.6.4. Call Masimo “domestically” at (800)326-4890, option #2, “internationally” at 949-297-7498, option #2 and ask for an RMA number.

5.6.5. A letter or email describing in detail any symptoms or difficulties experienced with the pulse oximeter. Please include the RMA number in the letter.

5.6.6. Warranty information – a copy of the invoice or other applicable documentation must be included.

5.6.7. Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if the warranty is in effect.

5.6.8. Ship-to and bill-to information.

5.6.9. Person (name, telephone/Telex/fax number, email and country) to contact for any questions about the repairs.

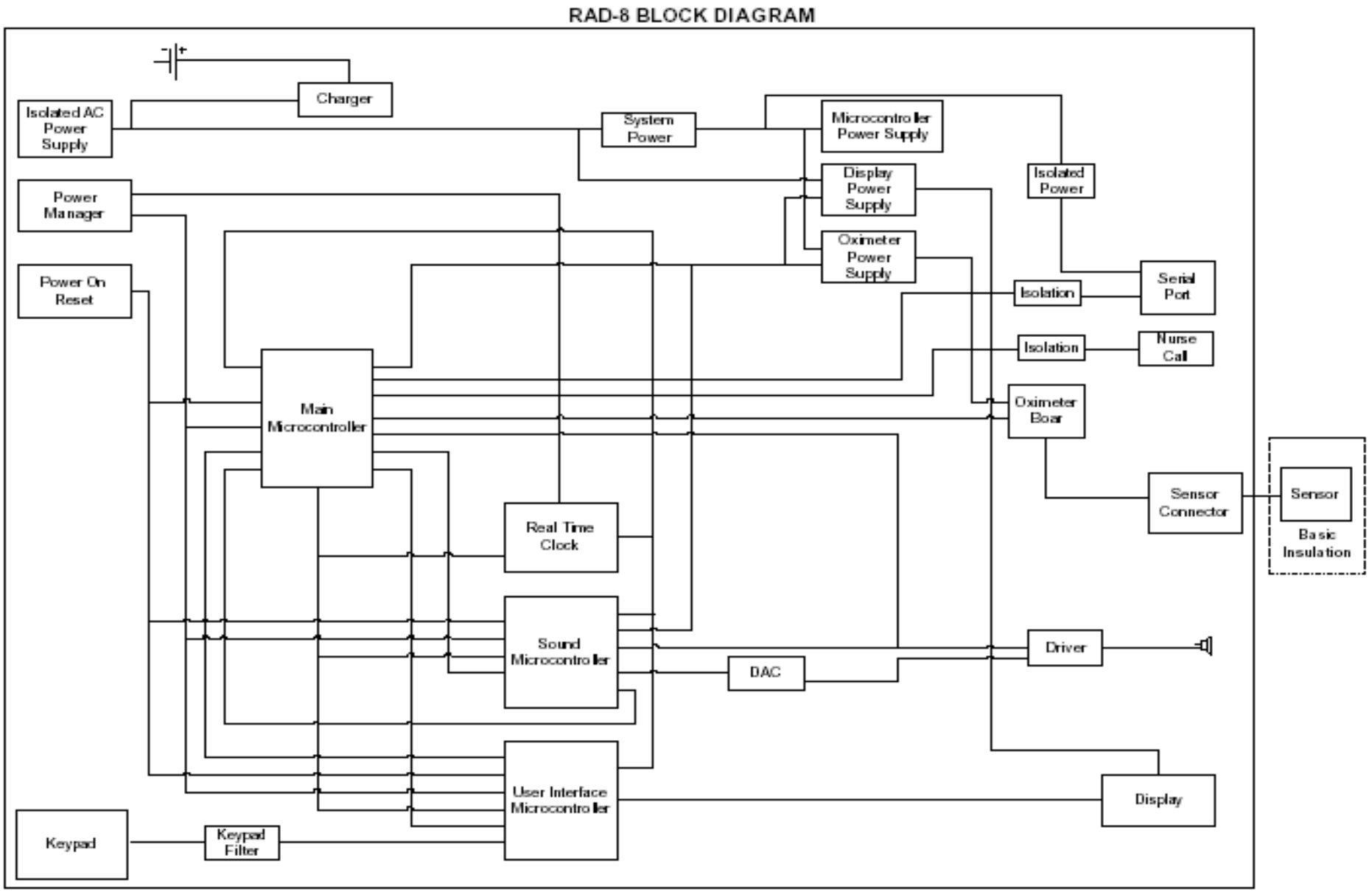
5.6.10. A document stating the oximeter has been decontaminated for bloodborne pathogens.

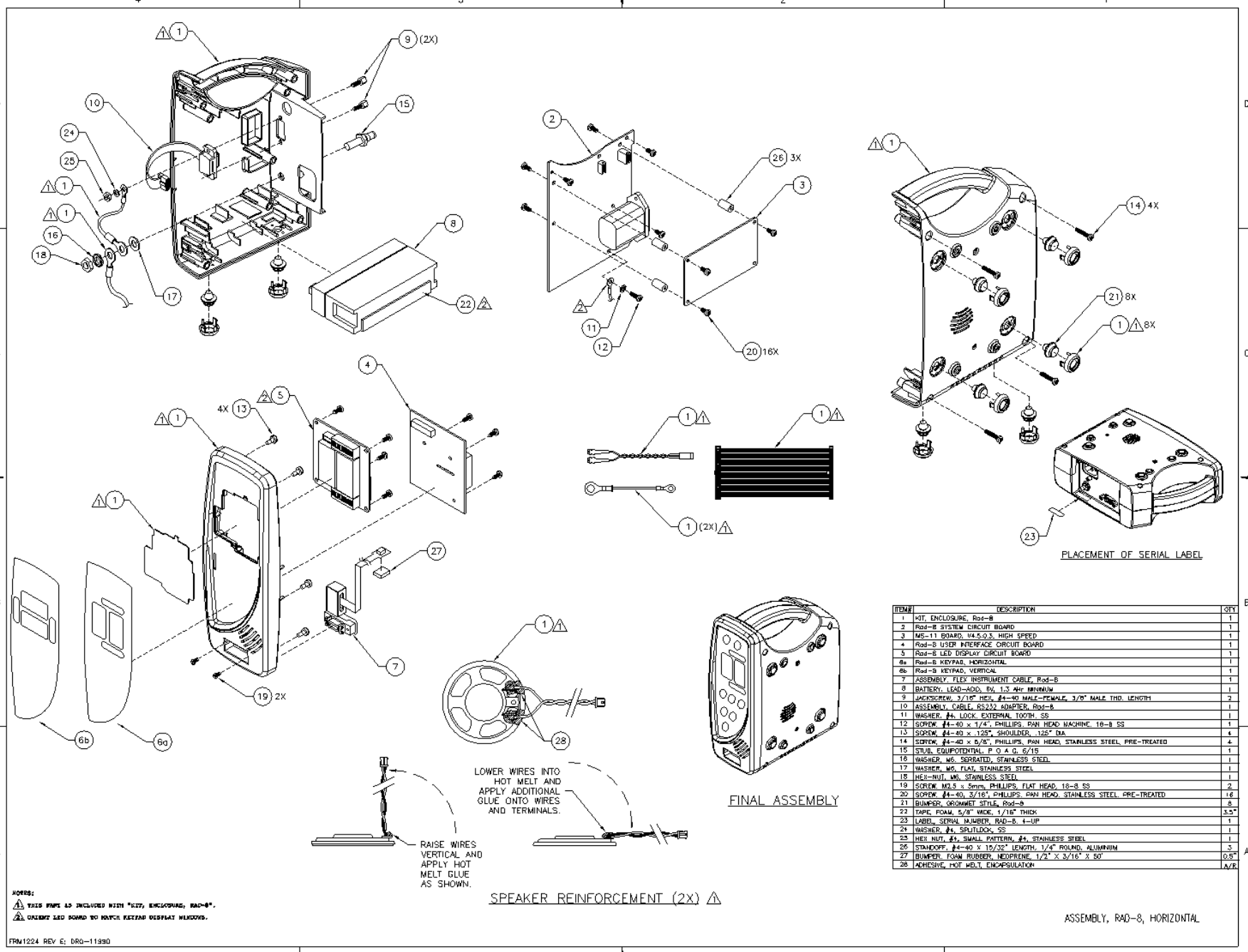
5.6.11. Return pulse oximeter to the following shipping address:

Masimo Corporation
40 Parker
Irvine, California
USA 92618

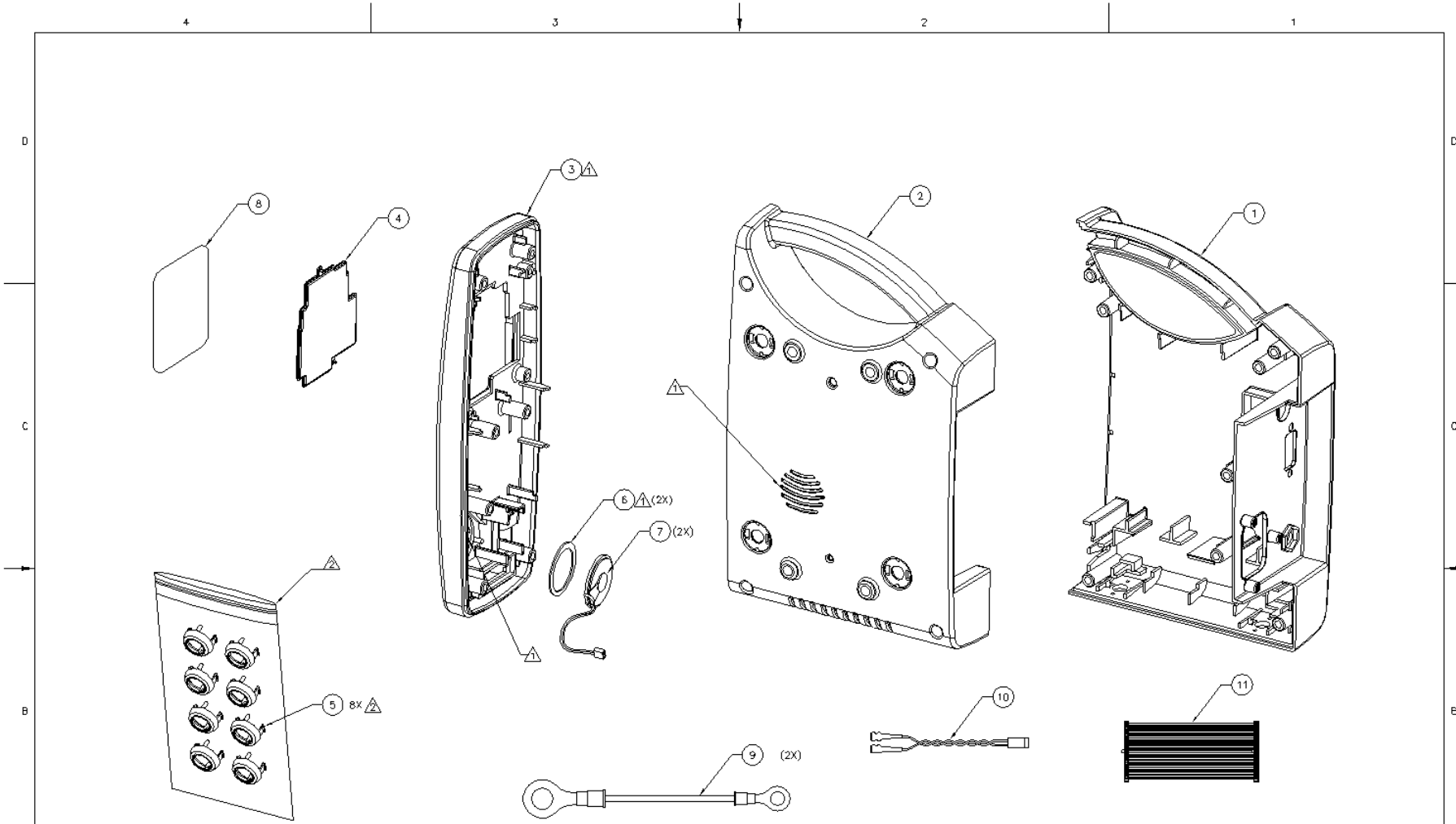
(Domestic Toll Free): 800-326-4890, option #2
(International): 949-297-7498, option #2
FAX: 949-297-7499

6. Drawings and Schematics




PLACEMENT OF SERIAL LABEL
FINAL ASSEMBLY
SPEAKER REINFORCEMENT (2X) ⚠
LOWER WIRES INTO HOT MELT AND APPLY ADDITIONAL GLUE ONTO WIRES AND TERMINALS.
RAISE WIRES VERTICAL AND APPLY HOT MELT GLUE AS SHOWN.
NOTES:
⚠ THIS PART IS INCLUDED WITH "KIT, ENCLOSURE, RAD-8".
⚠ ORIENT LED BOARD TO MATCH KEYPAD DISPLAY WINDOWS.
FRM1224 REV E; DRQ-11990
ASSEMBLY, RAD-8, HORIZONTAL

ITEM#	DESCRIPTION	QTY
1	KIT, ENCLOSURE, Rad-8	1
2	Rad-8 SYSTEM CIRCUIT BOARD	1
3	MS-11 BOARD, V4.5.0.3, HIGH SPEED	1
4	Rad-8 USER INTERFACE CIRCUIT BOARD	1
5	Rad-8 LED DISPLAY CIRCUIT BOARD	1
6a	Rad-8 KEYPAD, HORIZONTAL	1
6b	Rad-8 KEYPAD, VERTICAL	1
7	ASSEMBLY, FLEX INSTRUMENT CABLE, Rad-8	1
8	BATTERY, LEAD-ACID, 6V, 1.3 AHr MINIMUM	1
9	JACKSCREW, 3/16" HEX, #4-40 MALE-FEMALE, 3/8" MALE THD. LENGTH	2
10	ASSEMBLY, CABLE, RS232 ADAPTER, Rad-8	1
11	WASHER, #4, LOCK, EXTERNAL TOOTH, SS	1
12	SCREW, #4-40 x 1/4", PHILLIPS, PAN HEAD MACHINE, 18-8 SS	1
13	SCREW, #4-40 x .125", SHOULDER, .125" DIA	4
14	SCREW, #4-40 x 5/8", PHILLIPS, PAN HEAD, STAINLESS STEEL, PRE-TREATED	4
15	STUD, EQUIPOTENTIAL, P O A G, 6/15	1
16	WASHER, M6, SERRATED, STAINLESS STEEL	1
17	WASHER, M6, FLAT, STAINLESS STEEL	1
18	HEX-NUT, M6, STAINLESS STEEL	1
19	SCREW, M2.5 x 5mm, PHILLIPS, FLAT HEAD, 18-8 SS	2
20	SCREW, #4-40, 3/16", PHILLIPS, PAN HEAD, STAINLESS STEEL, PRE-TREATED	16
21	BUMPER, GROMMET STYLE, Rad-8	8
22	TAPE, FOAM, 5/8" WIDE, 1/16" THICK	3.5"
23	LABEL, SERIAL NUMBER, RAD-8, 4-UP	1
24	WASHER, #4, SPLITLOCK, SS	1
25	HEX NUT, #4, SMALL PATTERN, #4, STAINLESS STEEL	1
26	STANDOFF, #4-40 X 15/32" LENGTH, 1/4" ROUND, ALUMINUM	3
27	BUMPER, FOAM RUBBER, NEOPRENE, 1/2" X 3/16" X 50"	0.5"
28	ADHESIVE, HOT MELT, ENCAPSULATION	A/R



ITEM #	DESCRIPTION	QTY
1	TOP SHELL, ENCLOSURE, Rad-8	1
2	BOTTOM SHELL, ENCLOSURE, Rad-8	1
3	FRONT PANEL, ENCLOSURE, SILKSREEN, Rad-8	1
4	WINDOW, LED, Rad-8	1
5	FOOT, CAPTURE, Rad-8	8
6	GASKET, SPEAKER, Rad-8	2
7	ASSEMBLY, SPEAKER, Rad-8	2
8	GUARD, CLEAR PLASTIC, Rad-8	1
9	ASSEMBLY, CABLE, EARTH-GROUND, DOCKING STATION	2
10	ASSEMBLY, BATTERY CABLE, Rad-8	1
11	ASSEMBLY, RIBBON CABLE, Rad-8	1

NOTES:

1. INSERT SPEAKER GASKET, TRIM SPEAKER INTO RECESSES ON FRONT PANEL AND BOTTOM SHELL. HEAT STAKE SPEAKERS INTO BLACK USING ONLY 2 OPPOSITE POSTS FOR EACH SPEAKER.
2. INSERT WINDOW INTO FRONT PANEL AND SECURE WITH CLEAR PLASTIC GUARD.

KIT, ENCLOSURE, RAD-8

FRM1224 REV E; DRO-11990